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5630 FISHERS LN. RM 1061
ROCKVILLE,, MD 20852

RE: ALLOGRAFT TISSUE
DOCKET# 97-N-484S

NOV. 30, 1999

Dear Sirs:

I am a neurosurgery practitioner who does a considerable amount of spine surgery. I wish to strongly object to the regulation of bone allograft as a medical device. Clearly, this is- ridiculous. This is 'a biological product, which has, been carefully sterilized and preserved by various techniques for re-implantation into patients. Our need for these allografts can occur on a moments notice, and we need to have them available at all times. To back up at this stage and require clinical trials and other cumbersome regulatory procedures, would appear to me to be foolhardy and not in the best interest of patients care. Further more, unless obvious problems with quality control of these grafts can be shown in the current literature, which is extensive, there is no rationale in my opinion for proceeding along these lines.

I would ask you to firmly consider the sources of pressure for this legislation and to realize that they do not have to do directly with quality patient care.

Sincerely,

James E. Mc Lennan, M.D.

JEM/pm

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